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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/292,056	04/14/1999	JOEL S. GREENBERGER	PITT-1DIV	3040

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EXAMINER

BEISNER, WILLIAM H

ART UNIT	PAPER NUMBER
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1797

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/292,056	Applicant(s) GREENBERGER ET AL.	
	Examiner WILLIAM H. BEISNER	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2008 and 02 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,47-64,70,74-81,86-97,99,100,103,104 and 114-127 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,47-64,70,74-81,86-97,99,100,103,104 and 114-127 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/1/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 12/1/2008 has been considered and made of record.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1, 47-64, 70, 74-81, 86-97, 99, 100, 103, 104 and 114-127 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bisconte (US 4,800,164) in view of Price et al.(US 5,548,661).

With respect to claim 114, the reference of Bisconte discloses an apparatus that includes a housing (3a and/or 3b) having a biochamber (4 and/or 3a); an environment controlling mechanism (See column 2, line 29-33 and 43-48) for dynamically controlling the closed environment of the biochamber; a robotic arm (7) for dispensing and aspirating different material to each cell of the plurality of cells while the cells are disposed in the dynamically closed environment in the biochamber.

While the device of Bisconte discloses an automated controller and imaging components (See column 2, lines 34-42; and column 8, line 24, to column 9, line 6) for imaging the cells in the biochamber, the reference does not disclose that the imaging system is for determining which materials enhance the desired process in regard to each cell of the plurality of cells while the cells are disposed in the dynamically closed environment in the biochamber.

The reference of Price et al. discloses that it is known in the art to perform image analysis on live cells while held in a dynamically closed environment wherein each cell of the plurality of cells can be individually tracked over time (See Example 2, column 22, line 52, to column 25, line 43).

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In view of this teaching, it would have been obvious to one of ordinary skill in the art to modify the device of Bisconte so as to perform the live cell image analysis suggested by the reference of Price et al. for the known and expected result of employing the automated system of Bisconte and its associated advantages to perform other known live cell culture assays as suggested by the reference of Price et al. Note pages 4-5 of Applicants' remarks dated 1/18/2007 indicate that the "means for determining" includes structural components including a microscope mechanism, camera mechanism and a computer. The imaging section (6) of the reference of Bisconte includes optics, camera and image analyzer (See column 8, lines 59-68). The imaging section of the reference of Price et al. includes a microscope (102); camera (108) and processor (110, 112). As a result, the structures disclosed by the references of Bisconte and Price et al. meet the claimed "means for determining" in view of Applicants' clarification on the record as to what structures correspond to the means-plus-function language recited in the claim and the image analysis disclosed by the reference of Price et al. Note the image analysis system of the modified primary reference would be capable of ascertaining the occurrence of cell growth, differentiation, expression or secretion of a protein or hormone (See Example II of Price et al.).

With respect to claim 115, the reference of Bisconte et al. discloses that the image recognition system includes a microscope-equipped TV camera (See column 8, lines 59-62).

With respect to claim 116, the image recognition system is capable of determining cellular characteristics of the cells (See column 2, lines 29-42, of Bisconte et al. and processor (110,112) of Price et al.).

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With respect to claim 117, the system controller is capable of actuating the liquid handling system to provide media exchange with the cells (See column 10, lines 22-48).

With respect to claim 118, the liquid handling system is capable of aspirating, irrigating and dispensing media to the cells (See column 10, lines 22-48).

With respect to claim 119, the use of a plurality of pipette tips would have been well within the purview of one having ordinary skill in the art for the known and expected result of avoiding cross-contamination within the device.

With respect to claim 120, the stage (4,5) is capable of displacing at least one of the housing containers (wells) with respect to the liquid handling system and image recognition system.

With respect to claim 121, the image recognition system is capable of determining cellular characteristics and the system controller is capable of regulating the biochamber and liquid handling system in response (See the processor (110,112) of Price et al.).

With respect to claim 122, the biochamber is capable of being displaceable to both the liquid handling system (4) and image recognition system (24).

With respect to claim 123, the biochamber can be moved in the X and Y directions (See stage (4,5)) and the liquid handling system (7) and image recognition system (6) can be moved in the Z direction.

With respect to the means for automatically determining recited in claims 1, 47-57, 62-64, 70, 74, 75, 79, 80, 95, 97, 100 and 124-127, since the imaging structures disclosed by the references of Bisconte and Price et al. meet the same structures that correspond to the means-plus-function language of claim 114, the imaging structures disclosed by the reference of

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Bisconte and Price et al. are capable of functioning in the manner intended by the language of claims 1, 47-57, 62-64, 70, 74, 75, 79, 80, 95, 97, 100 and 124-127. Note a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

With respect to claim 94, 96, 103 and 104, since the imaging structures disclosed by the references of Bisconte and Price et al. meet the same structures that correspond to the means-plus-function language of claim 114, the imaging structures disclosed by the reference of Bisconte and Price et al. are capable of functioning in the manner intended by the language of claims 94, 96, 103 and 104. Note a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

With respect to claims 58, 77, 78 and 125-127, the reference of Bisconte et al. discloses an apparatus that includes a biochamber (4) includes a plurality of wells (25) and the robotic mechanism (7)) can include a diagnostic mechanism.

With respect to claims 76, 81, 86-93 and 99, the liquid handling system is capable of aspirating, irrigating and dispensing media to the cells (See column 10, lines 22-48). Also, the use of a plurality of pipette tips would have been well within the purview of one having ordinary skill in the art for the known and expected result of avoiding cross-contamination within the device.

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With respect to claim 59-61, 64 and 74-76, since the imaging structures disclosed by the references of Bisconte and Price et al. meet the same structures that correspond to the means-plus-function language of claim 114, the imaging structures disclosed by the reference of Bisconte and Price et al. are capable of functioning in the manner intended by the language of claims 59-61, 64 and 74-76. Note a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Terminal Disclaimer

6. The terminal disclaimers filed on 1/2/2009 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6,008,010 and U.S. Application No. 10/114,892 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Response to Arguments

7. With respect to the rejection of Claims 1, 47-64, 70, 74-81, 86-97, 99, 100, 103, 104 and 124-127 under 35 U.S.C. 102(b) as being anticipated by Funakubo et al.(US 5,106,584), this rejection has been withdrawn in view the amendments to the claims and related comments filed 12/1/2008. However, new grounds of rejection have been make over the combination of the reference of Bisconte (US 4,800,164) in view of Price et al.(US 5,548,661).

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM H. BEISNER whose telephone number is (571)272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/William H. Beisner/
Primary Examiner
Art Unit 1797**

WHB